

DEPARTMENT OF HEALTH SERVICES

GENETIC DISEASE BRANCH
2151 BERKELEY WAY, ANNEX 4
BERKELEY, CA 94704



Newborn Screening Program
Tandem Mass Spectrometry (MS/MS) Research Project
Suggestions for Hospital Staff

Give mother/parents a copy of the revised booklet entitled *Important Information for Parents About the Newborn Screening Test* and provide the following information. (This information can be given to women prior to or after delivery, but should not be given during active labor.)

This booklet, developed by the Newborn Screening Program, explains both the current mandatory newborn screening program (in the first few pages of the booklet on the white pages) and the supplemental mass spectrometry research testing (in the purple pages in the center of the booklet). [The booklet is in both English and Spanish (also available in Chinese, Vietnamese, Cambodian, and Korean by calling (510) 540-3295.)] You should have received it from your obstetrician a few months ago and discussed the project with him/her.

If questioned regarding the supplemental project, provide the following information.

The California Department of Health Services (DHS) Newborn Screening Program is in the process of adding tests to pick up additional disorders on the Newborn Screening panel. The Department is conducting a research study to determine which of these metabolic disorders should be added to the mandatory newborn screening tests currently performed on newborns. Several other states already test or are in the process of preparing to test for some of these disorders. DHS is asking all women, such as you, whose newborn's newborn screening specimen is collected on or after January 7, 2002 if they wish to participate in this study. The study involves testing the blood that is already taken from your newborn (NO ADDITIONAL BLOOD WILL BE TAKEN) for about 30 additional disorders. If the results on your baby's blood are negative (no unusual findings), neither you nor your pediatrician will be notified. But if some of the results are "unusual" or have a different pattern than the normal pattern, your pediatrician will be contacted to arrange for additional studies on your baby.

Your participation in the supplemental research testing is voluntary. We will ask you to sign a consent form before the blood is taken from your baby and indicate whether or not you wish to participate. The form you will be asked to sign is in the middle of the booklet for you to review. A color-coded sticker will be placed on the Test Request Form that accompanies your baby's blood specimen to indicate your participation ("YES") or your refusal ("NO"). If you haven't signed the consent form by the time the blood is taken then a "NO" sticker will be affixed and the specimen will not be part of the supplemental screening program.

If you have any additional questions about the research program, please write them down so that you can have all the information you need before you sign the consent form. You may also call the California Newborn Screening Program toll free at (866) 954-BABY (954-2229).